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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,436	06/30/2003	Istvan Toth	36677.11	9341
27683 7590 06/14/2007 HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202			EXAMINER KRISHNAN, GANAPATHY	
			ART UNIT 1623	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

The amendment filed 4/4/2007 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 2 and 14-15 have been canceled.
2. New Claim 38 has been added.
3. Claims 1, 5-7, 9, 12, 19, 28 and 35-37 have been amended.
4. Remarks drawn to rejections under 35 USC 103.

Claims 1, 3-13 and 16-38 are pending in the case. Claims 18 and 20-23 have been withdrawn. Claims 1, 3-13, 16-17, 19 and 24-38 are under consideration.

The following rejection necessitated by amendment is made of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-13, 16-17, 19 and 24-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekany et al (Peptides, 1996, 331-32) of record in view of Neubert (Pharmaceutical Research, 1989, 6(9), 743-749; document C10 in IDS of 218/2005) newly cited.

Dekany et al disclose a lipidic moiety containing sugar compound (page 332, structural formula 2). In this structure the lipidic moiety (shown to the right in the structure; L in instant claim 1) is attached to a monosaccharide (S in the instant claims) via a linker (NH group). The sugar bearing the lipidic moiety is attached to another sugar. A sugar molecule is a therapeutically useful molecule. Structure 2 of Dekany meets the limitations of instant formula I for W being absent.

The linker, NH in structure 2 of Dekany, is attached to the sugar unit through the glycosidic position. The term glycosidic position is not defined by the claim. Hence any position on the sugar moiety is interpreted as a glycosidic position. Since the attachment of the lipidic moiety to the sugar is via a nitrogen atom and a CONH group is present, the attachment to the monosaccharide is via an N-glycoside and an amide bond. The linker, NH, is attached to the lipidic moiety $C(O)CH-(NHR^2)-(CH)_2-CH_3$ group in structure 2 of Dekany, via an amide bond.

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In structure 2 of Dekany lipidic moiety L is composed of the group $-C(O)CH-(NHR^2)-(CH)_2-CH_3$. This structure is same as structure IIa for R_1 = hydrogen and R_2 = linear alkyl chain having 16 carbons and both R_1 and R_2 are not hydrogens at the same time. The lipid moiety in structure 2 of Dekany has an NHR^2 group attached to it, which can be charged. In structure 2 of Dekany the sugar unit in the middle (mono saccharide) is attached to a lipidic moiety containing one lipoaminoacid meeting the structural formula IIa in instant claim 12. Dekany suggests the coupling of the conjugate of his invention to peptides and drugs (page 332, paragraph below structure 2). The physico chemical properties of the conjugates were modified by varying the nature and the number of sugars, the number of lipoaminoacids or the length of their alkyl chain. According to Dekany complexation of the conjugate (structure 2, page 332) to drugs and peptides will enhance the water solubility in drug delivery and increase the immunogenicity of synthetic peptides. However, Dekany does not teach compounds wherein the sugar moiety is substituted with alkyl or heteroalkyl spacers carrying functional groups that can carry a charge.

According to Neubert the lipophilicity of drugs can be increased by ion pair formation with lipophilic counterions (page 743, first two lines of the first full paragraph on the right column and conclusion at page 746). Neubert also teaches that the key is the use of specific lipophilic counter ions with a convenient physiological compatibility (page 746, last two lines). From this teaching of Neubert one of ordinary skill in the art will recognize that in order to increase the bioavailability of drugs ionic complexes that have ion pairs are important and the more ion pairs that form the more the solubility. Since Dekany teaches compounds that have a sugar and lipophilic moiety, both of which are biocompatible and have alkyl groups that can carry a charge (amino groups), it would be logical to have more of such alkyl chains with

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functional groups that are capable of carrying a charge. This would result in the formation of several ion pairs, which in turn would increase the bioavailability and transport of drugs. A logical step would be to have these additional charge bearing groups on the carbohydrate moiety of the compound of Dekany.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make complexes of formula I and their compositions as instantly claimed with a reasonable expectation of success since the prior art teaches the preparation of such complexes using the components as instantly claimed. Introduction of alkoxy groups containing other functional groups is well known to one of ordinary skill in the art.

One of ordinary skill in the art would be motivated to make such compounds and compositions since such a complex with drugs and peptides increases their water solubility and hence would be useful in drug delivery as taught by Dekany. It is well within the purview of one of ordinary skill in the art to extend this to mono and oligosaccharides and several drugs for the purpose of enhanced drug delivery.

Response to Applicants Remarks

Applicants have amended the instant claims to include the component W in formula (I) and argue that Dekany does not teach the complex comprising O-alkyl groups and related spacer groups attached to the mono or oligosaccharide. The rejection above, necessitated by amendment is advanced.

Conclusion

Claims 1, 3-13, 16-17, 19 and 24-38 are rejected

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

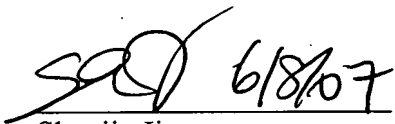
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

Handwritten signature of Shaojia Jiang and the date 6/18/07.

Shaojia Jiang
Supervisory Patent Examiner
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